K 040545

APR 2 2 2004

510(k) Summary

Submitted on behalf of:

Otter (China) Technology, Co. Ltd.
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CONTACT PERSON: **Elaine Duncan**

DATE PREPARED: February 27, 2003, revised April 16, 2004

TRADE NAME: **Otter Safety Syringe**
COMMON NAME: Safety Syringe

SUBSTANTIALLY EQUIVALENT TO:

The Otter Safety Syringe is substantially equivalent to the Duopro Safety Syringe and the SecureGard Retractable Safety Syringe because these devices also retract the needle into the barrel of the syringe and the SEZ Safety Syringe which also crumples the needle. The Nipro hypodermic needle is a predicate for the Otter Syringe as these are the same as the needles used on the Otter Syringe.

DESCRIPTION of the DEVICE:

The Otter Safety Syringe is an integrated needle and piston syringe with an innovative anti-needlestick mechanism. The design incorporates the ideal features desired in a safety syringe. No special techniques are required to use the safety mechanism. The mechanism allows clear visualization of the injection site at all times. The mechanism clearly shows that the needle has been crushed within the syringe barrel. After standard techniques for injection, the plunger is withdrawn completely into the barrel. A forward compression of the plunger again and the needle is crushed within the puncture-resistant barrel. This renders the needle unusable and safe from accidental needle sticks.

INDICATIONS FOR USE:

The Otter Safety Syringe is a sterile, single-use, disposable and non-reusable, manual retractable safety syringe intended for injection of fluids into the body, while reducing the risk of sharps injuries and the potential for syringe reuse.

SUMMARY of TESTING:

The Otter Safety Syringe has been shown to meet internationally recognized standards for syringe performance and labeling characteristics. In addition, clinical testing in China and simulated use testing in US clinics by qualified healthcare professionals proved the Otter Safety Syringe performs reliably and in accordance with the high expectations for safety syringes set by FDA and healthcare organizations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2004

Otter (CHINA) Technology Company Limited
C/O Ms. Elaine Duncan
Paladin Medical, Incorporated
P.O. Box 560
Stillwater, Minnesota 55082

Re: K040545
Trade/Device Name: Otter Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: February 27, 2004
Received: March 2, 2004

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040545

Indications for Use

510(k) Number (if known): K040545

Device Name: Otter Safety Syringe

Indications For Use:

The Otter Safety Syringe is a sterile, single-use, disposable and non-reusable, manual retractable safety syringe intended for injection of fluids into the body, while reducing the risk of sharps injuries and the potential for syringe reuse.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Irene Raveau for ADW 4/11/04
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K040545